K023580

510(k) Summary

Trade Name: **Sterngold Acid Etch Dental Implant System**

JAN 17 2003

Sponsor: Sterngold
23 Frank Mossberg Drive
Attleboro, MA 02703

Device Generic Name: Dental endosseous implant system

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class III

Product Code: DZE (21CFR872.3640)

Predicate Devices:
The Sterngold Acid Etch Dental Implants are substantially equivalent to other currently marketed dental implant systems that have been cleared by FDA through the 510(k) Premarket Notification process, including the Implant Innovations Osseotite Dental Implant System and the Nobel Biocare MKIII Dental Implant System.

Product Description:
The Sterngold Acid Etch Dental Implant System consists of standard, external-hex, self-tapping, double-threaded, root-form endosseous implants that will be available is a variety of sizes to suit individual user/patient needs. Each implant is provided with a cover screw. The implants are manufactured from pure, implant-grade titanium. The external surface of the implants (excluding the top three threads, the neck and the implant head) is lightly acid etched to remove any traces of contaminants remaining from the manufacturing process, and to achieve a slightly roughened microsurface to aid in implant osseointegration.

The proposed implants are compatible with standard, regular platform (4.1mm), external-hex (anti-rotational) abutments such as the currently marketed Sterngold-ImplaMed, Implant Innovations, and Branemark System (Nobel Biocare). A specially-designed SternTwist internal grip insertion tool will be available as an accessory to the Acid Etch Implants.

The Sterngold Acid Etch Implants will be available in the following sizes:

Diameter (mm)	Overall Length (mm)
3.75	8.5, 10, 11.5, 13, 15, 18
4.00	8.5, 10, 13, 15
5.00	8.5, 10

Indications for Use:
The Sterngold Acid Etch Dental Implant System consists of endosseous dental implants indicated:
- For implantation into any area of the fully endentulous maxilla and mandible for the support of a removable or fixed dental prosthesis
- For implantation into any area of the partially endentulous maxilla and mandible for the support of a removable or fixed dental prosthesis
- For single tooth or multiple unit prosthesis

Safety and Performance:
This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket

Notifications." In support of this 510(k), Sterngold has provided information to demonstrate conformity with the following standards:

- ***Overview of Information Necessary for Premarket Notification Submissions for Endosseous Implants*** (FDA Guidance)
- ***Information Necessary for Premarket Notification Submissions for Screw-Type Endosseous Implants*** (FDA Guidance; December 9, 1996)

Conclusion:
Based on their indications for use, technological characteristics, and comparison to predicate devices, the Sterngold Acid Etch Dental Implant System has been shown to be safe and effective for the product's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

Sterngold
C/O Ms. Pamela Papineau
Delphi Medical Consulting, Incorporated
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K023580
Trade/Device Name: Sterngold Acid Etch Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant System
Regulatory Class: III
Product Code: DZE
Dated: October 21, 2002
Received: October 24, 2002

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

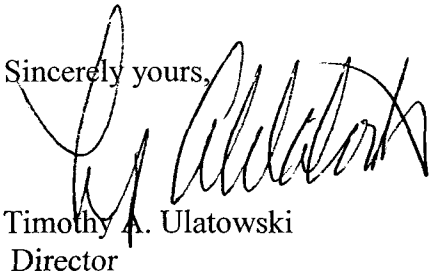
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023580

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023580